510(k) Summary
for
Maxx Orthopedics Freedom® Tibial Knee Components

1. SPONSOR

Maxx Orthopedics, Inc.
2260 Butler Pike
Suite 100
Plymouth Meeting, PA 19462

APR - 7 2009

Contact Person: Nach Dave
Telephone: 732-718-1385

Date Prepared: March 26, 2009

2. DEVICE NAME

Proprietary Name:	Freedom® Metal Backed Tibial Component
Common/Usual Name:	Metal-backed tibial component
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

3. PREDICATE DEVICES

- Exactech Optetrak Total Knee Tibial Components subject of K030686.

4. DEVICE DESCRIPTION

The Maxx Orthopedics' Freedom® Metal Backed Tibial Component and Ultra High Molecular Weight Polyethylene (UHMWPE) insert are compatible with the Maxx Orthopedics Freedom® Total Knee System subject of K082019. The Maxx Orthopedics' Freedom® Total Knee System subject of K082019 is comprised of a femoral component, tibial component and patella component.

The Freedom® Metal Backed Tibial Component and UHMWPE insert are intended to be used with the Freedom® Total Knee System. The proposed metal backed Tibial Component and UHMWPE insert will be used in place of the all-poly tibial component with the Freedom® Total Knee System.

The proposed metal backed tibial component consists of a cobalt-chromium-molybdenum tray, and the insert is made from UHMWPE. These components are intended for cemented application to replace the articulating surface of the proximal tibia in a measured resection.

The tibia base components are designed with a keel portion which extends into the proximal tibial medullary canal. The more distal portion of the tibial base has a flat plate that rests on the patient's tibial plateau region. On the underside of this plate are cement recesses allowing allow for cement interdigitation which helps to provide rotational stability. The Freedom® Knee tibial inserts have an interlocking relation to the tibial base. The Freedom® Knee femoral components articulate with the bearing base (proximal) surface of the tibial inserts. The articulating surface of these inserts is identical to the articulating surface of the all-poly liner components mentioned in the already cleared Freedom® Total Knee System (K082019).

5. INTENDED USE

The Freedom® Metal Backed Tibial Component consists of a cobalt-chrome molybdenum (CoCrMo) tray and a UHMWPE insert that are designed to be used with the Freedom Total Knee System. The Maxx Orthopedics' Freedom® Total Knee System is indicated for patients with severe knee pain and disability due to:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, and/or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods.

The Maxx Orthopedics' Freedom Total Knee System is intended for cemented use only. This device is for single use only.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Maxx Orthopedics' Freedom® Metal Backed Tibial Component and the predicate devices are identical in that they all consist of a cobalt-chrome molybdenum (CoCrMo) tray and a UHMWPE insert.

Both the proposed component and the predicate devices have been designed to mimic the normal knee geometry. Both the proposed and predicate devices are available in a variety of tibial tray and insert sizes that are intended to mimic normal human anatomy. The articulating surface of the proposed Maxx Orthopedics Freedom® femoral and tibial components, are similar to the articulating surface of the predicate systems and are functionally equivalent devices. Both the proposed and predicate

devices are made of biocompatible materials and are technological designed and identical in materials.

7. PERFORMANCE TESTING

Mechanical and functional testing described in K082019 and in Section 8 demonstrates that the Freedom® Metal Backed Tibial Component are mechanically and functionally similar to the parent Freedom UHMWPE Tibial Component and other legally marketed knee systems. Evaluations were performed to determine the material and mechanical characteristics of the Maxx Orthopedics' Freedom® Metal Backed Tibial Component and the Freedom® Total Knee System according to the Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA. The verification and validation testing performed which demonstrated that the Metal Backed Tibial Component functions as intended and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Maxx Orthopedics, Inc.
% Mary McNamara-Cullinane, RAC
Senior Regulatory Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K090411
Trade/Device Name: Freedom Total Knee Metal Backed Tibial Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Class: Class II
Product Code: JWH
Dated: March 26, 2009
Received: March 27, 2009

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090411

Device Name: Maxx Orthopedics' Freedom® Metal Backed Tibial Component

Indications for Use:

The Freedom® Metal Backed Tibial Component consists of a cobalt-chrome molybdenum (CoCrMo) tray and a UHMWPE insert that are designed to be used with the Freedom® Total Knee System. The Maxx Orthopedics' Freedom® Total Knee System is indicated for patients with severe knee pain and disability due to:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
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The Maxx Orthopedics' Freedom Total Knee System is intended for cemented use only. This device is for single use only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090411 /S001